

REMARKS

The following remarks are responsive to the Office Action dated July 16, 2003.

The Examiner has allowed claim 21. Claims 1-43 are pending in this application.

Claims 1, 10, 12, 22, 23, 29, 32, and 37 have been amended to clarify the invention. Applicants do not acquiesce to the subject matter of the claims prior to this Amendment, and reserve the right to pursue the subject matter of those claims.

Claims 42 and 43 have been newly added by this Amendment. No new matter has been introduced by the newly added claims or claim amendments made herein.

35 U.S.C. § 112 REJECTION OF CLAIMS 29 and 37

The Examiner rejected claims 29 and 37 under 35 U.S.C. § 112, as indefinite. Applicants amended claims 29 and 37 to correct antecedent basis informalities. Applicants respectfully submit that, with the entering of the requested amendments, the rejection is now moot.

35 U.S.C. § 102(B) REJECTION OF CLAIMS 1-5, 8-10, 12-20, 22-26, 29, AND 32-39

The Examiner rejected claims 1-5, 8-10, 12-20, 22-26, 29, and 32-39 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,772,586 to Heinonen et al. ("Heinonen"). (OA, ¶5). Applicants respectfully traverse this rejection and submit that the claims, as amended, are patentable over Heinonen.

INDEPENDENT CLAIM 1 IS PATENTABLE OVER HEINONEN

In the Office Action, the Examiner cites to various sections of Heinonen as allegedly showing all of the limitations of claim 1. Applicants respectfully submit, however, that Heinonen does not disclose, teach, or suggest at least "a sampling module comprising a lancet, a driving mechanism, and a sample port, wherein said sampling port receives at least one body fluid directly from a tissue punctured with said lancet driven by said driving mechanism," as recited in claim 1. In contrast,

Heinonen discloses a multi-step process of receiving body fluid that involves patient handling of the body fluid. (Heinonen, Col. 5, lines 20-27). For example, in Heinonen, after the patient pricks the skin "the patient thereafter pulls out a strip 16 that is known per se and that is placed for example on a reel 15 in the measuring unit 11, the strip being impregnated with the drop of blood." (Heinonen, Col. 5, lines 23-27). This, however, does not show a sample port receiving "at least on **body fluid directly from a tissue punctured**." Instead, Heinonen teaches a body fluid being received through a strip impregnated with blood. Thus, Applicants submit that claim 1 is patentable over Heinonen.

INDEPENDENT CLAIM 10 IS PATENTABLE OVER HEINONEN

In the Office Action, the Examiner cites to various sections of Heinonen as allegedly showing all of the limitations of claim 10. Applicants respectfully submit, however, that Heinonen does not disclose, teach, or suggest at least "obtaining a body fluid from a tissue punctured with a lancet, the lancet being driven by a driving mechanism, wherein the body fluid from the tissue flows directly into a cartridge having said lancet" as recited in claim 10. In contrast, Heinonen discloses a multi-step process of receiving body fluid that involves patient handling of the body fluid. (Heinonen, Col. 5, lines 20-27). For example, in Heinonen, after the patient pricks the skin "the patient thereafter pulls out a strip 16 that is known per se and that is placed for example on a reel 15 in the measuring unit 11, the strip being impregnated with the drop of blood." (Heinonen, Col. 5, lines 23-27). This, however, does not show obtaining a body fluid "wherein the body fluid from the tissue flows directly into a cartridge having said lancet". Instead, Heinonen, teaches a body fluid being received through a strip impregnated with blood. Thus, Applicants submit that claim 10 is patentable over Heinonen.

INDEPENDENT CLAIMS 12 AND 24 ARE PATENTABLE OVER HEINONEN

In the Office Action, the Examiner cites to various sections of Heinonen as allegedly showing all of the limitations of claims 12 and 22, as amended. Applicants respectfully submit, however, that Heinonen does not disclose, teach or suggest at least “a sampling module comprising a sample port for receiving at least one body fluid directly from a tissue, said sampling module housed in a cartridge,” as recited in claims 12 and 22. In contrast, Heinonen discloses a multi-step process of receiving body fluid that involves patient handling of the body fluid. (Heinonen, Col. 5, lines 20-27). For example, in Heinonen, after the patient pricks the skin “the patient thereafter pulls out a strip 16 that is known per se and that is placed for example on a reel 15 in the measuring unit 11, the strip being impregnated with the drop of blood.” (Heinonen, Col. 5, lines 23-27). This, however, does not show a sampling module “receiving at least one **body fluid directly from a tissue**.” Instead, Heinonen, teaches a body fluid being received through a strip impregnated with blood. Thus, Applicants submit that claims 12 and 22 are patentable over Heinonen.

INDEPENDENT CLAIM 23 IS PATENTABLE OVER HEINONEN

In the Office Action, the Examiner cites to various sections of Heinonen as allegedly showing all of the limitations of claim 23. Applicants respectfully submit, however, that Heinonen does not disclose, teach or suggest at least “obtaining a body fluid directly from a tissue puncture created by a lancet, wherein the lancet is driven outward from a cartridge by a lancet driver and wherein the body fluid from the tissue puncture flows into the cartridge,” as recited in claim 23. In contrast, Heinonen discloses a multi-step process of receiving body fluid that involves patient handling of the body fluid. (Heinonen, Col. 5, lines 20-27). For example, in Heinonen, after the patient pricks the skin “the patient thereafter pulls out a strip 16 that is known per se

and that is placed for example on a reel 15 in the measuring unit 11, the strip being impregnated with the drop of blood." (Heinonen, Col. 5, lines 23-27). This, however, does not show "obtaining a **body fluid directly from a tissue punctured with a lancet.**" Instead, Heinonen, teaches a body fluid being received through a strip impregnated with blood. Thus, Applicants submit that claim 23 is patentable over Heinonen.

INDEPENDENT CLAIM 32 IS PATENTABLE OVER HEINONEN

In the Office Action, the Examiner cites to various sections of Heinonen as allegedly showing all of the limitations of claim 32. Applicants respectfully submit, however, that Heinonen does not disclose, teach or suggest at least "a sample pathway for receiving at least one body fluid directly from a tissue puncture formed by said lancet, said pathway contained within the cartridge," as recited in claim 32. In contrast, Heinonen discloses a multi-step process of receiving body fluid that involves patient handling of the body fluid. (Heinonen, Col. 5, lines 20-27). For example, in Heinonen, after the patient pricks the skin "the patient thereafter pulls out a strip 16 that is known per se and that is placed for example on a reel 15 in the measuring unit 11, the strip being impregnated with the drop of blood." (Heinonen, Col. 5, lines 23-27) This, however, does not show a sample pathway "receiving at least one **body fluid directly from a tissue puncture formed by said lancet.**" Instead, Heinonen, teaches a body fluid being received through a strip impregnated with blood. Thus, Applicants submit that claim 32 is patentable over Heinonen.

DEPENDENT CLAIMS 11, 13, AND 15-20 ARE PATENTABLE OVER HEINONEN

Claims 2-5, 8, and 9 each depend from independent claim 1, and are thus allowable for at least the reasons set forth in connection with claim 1 from which they depend. Claims 13-20 each depend from independent claim 12, and are thus

allowable for at least the reasons set forth in connection with claim 12 from which they depend. Claims 24-26, and 29 each depend from independent claim 23, and are thus allowable for at least the reasons set forth in connection with claim 23 from which they depend. Claims 33-39 each depend from independent claim 32, and are thus allowable for at least the reasons set forth in connection with claim 32 from which they depend.

35 U.S.C. §103 REJECTION OVER HEINONEN IN VIEW OF SKILL IN THE ART

The Examiner rejected of claims 27, 28, 30, 31, 40, and 41 under 35 U.S.C. § 103(a) as allegedly unpatentable over Heinonen in view of skill in the art at the time the invention was made (OA, ¶8). As discussed above, Applicants respectfully submit that claims 24 and 32 are patentable over Heinonen. Accordingly, claims 27, 28, 30, 31, 40, and 41, which depend from claims 23 and 32, should be in condition for allowance.

Further, Applicants respectfully challenge the Examiner's assertion that the use of a electromechanical or and electrical driver as desired to better control the lancing process was a well known substitution for the mechanical driver as disclosed by Heinonen at the time of the Applicants' invention. (OA, ¶8). Accordingly, Applicants request that the Examiner cite a prior art reference to support his assertion, as required by MPEP § 2144.03.

ALLOWABLE SUBJECT MATTER

The Examiner allowed claim 21. Claims 6, 7, and 11 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. New claims 42 and 43 incorporate dependent claims 6 and 7 into their independent base claim and are therefore allowable over the prior art of record.

CONCLUSION

In view of the foregoing remarks, Applicants submit that claims 1-43 are neither anticipated nor rendered obvious in view of the prior art of record. Applicants therefore request the Examiner's reconsideration and reexamination of the application, and the timely allowance of claims 1-43.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 50-1078.

Respectfully submitted,

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Dated: October 16, 2003

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EV 351294015 US